

GR
**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

LUPIN ATLANTIS HOLDINGS, : CIVIL ACTION
Plaintiffs, :
: :
v. : :
: :
RANBAXY : APR 21 2011
LABORATORIES, Ltd., et al., : Clerk
Defendants. : :
: :
No. 10-3897 :
APR 21 2011
MCHALE, Clerk
Dep. Clerk

MEMORANDUM

PRATTER, J.

APRIL 20, 2011

INTRODUCTION

Lupin Atlantis Holdings (“Lupin Atlantis”) has sued Ranbaxy Laboratories, Ltd., Ranbaxy Pharmaceuticals, Inc., and Ranbaxy, Inc. (collectively, “Ranbaxy”), alleging that Ranbaxy has infringed upon a patent licensed to Lupin Atlantis. Lupin Atlantis has also sued Ethypharm, the owner of the disputed patent, alleging that Ethypharm has breached a contractual obligation to cooperate with Lupin Atlantis in suing Ranbaxy. All of the parties to this case are pharmaceutical companies.

Ranbaxy moves to dismiss Lupin Atlantis’s infringement claim on the ground that the Complaint fails to state a claim against Ranbaxy upon which relief can be granted. For the reasons set forth below, the Motion to Dismiss will be denied.

FACTUAL AND PROCEDURAL BACKGROUND

For the purposes of a motion to dismiss, facts alleged in the complaint are considered to be true. On that basis, the facts are as follows.

Lupin Atlantis accuses Ranbaxy of infringing upon U.S. Patent 7,101,574 (“the ‘574 Patent”), which was issued by the U.S. Patent and Trademark Office in September of 2006, and is entitled “Pharmaceutical Composition Containing Fenofibrate and the Preparation Method.” Lupin also claims that Ethypharm, the actual owner of the ‘574 Patent, has licensed Lupin Atlantis to enforce the ‘574 Patent in the event that another company files Abbreviated New Drug Application (“ANDA”) for a drug that infringes on the ‘574 Patent.¹

According to Lupin Atlantis, the ‘574 Patent discloses and claims a drug that contains fenofibrate. Lupin Atlantis is the owner of an approved New Drug Application (“NDA”) for a cardiovascular drug called Antara, which contains some amount of “micronized” fenofibrate as an active ingredient.

Lupin Atlantis’ claim against Ranbaxy arises under the Hatch-Waxman Act of 1984, which was devised to provide a statutory framework for resolving patent disputes between pioneering and generic drug manufacturers. Under Hatch-Waxman, a generic drug manufacturer may seek approval from the Food & Drug Administration (“FDA”) to market a generic version of a pioneer drug by filing an ANDA.²

If the generic drug manufacturer seeks to market its proposed generic drug prior to the

¹ Lupin Atlantis has also sued Ethypharm in this action, although Ethypharm has not moved to dismiss. Lupin Atlantis alleges that while Ethypharm has licensed Lupin Atlantis to enforce the ‘574 Patent, and is contractually obligated to cooperate with Lupin Atlantis in filing an enforcement suit, including (if necessary) joining such a suit as a co-plaintiff, Ethypharm has not agreed to join Lupin Atlantis in suing Ranbaxy.

² By filing an ANDA, a generic manufacturer can bypass the ordinary FDA requirement that it prove that a drug is safe and efficacious, so long as it can demonstrate that the ANDA generic is “bioequivalent” to an already-approved pioneer drug. *Astrazeneca Pharms. LP v. Apotex Corp.*, 2010 U.S. Dist. LEXIS 132727 at *5-6 (E.D.Pa. 2010).

expiration of a patent that covers the pioneer manufacturer's drug, it must include a so-called "Paragraph IV certification" in its ANDA.³ Under these circumstances, the generic drug maker must also send a Paragraph IV notice letter to the pioneer drug maker, explaining in detail why its ANDA drug does not infringe on the patent.⁴

By statutory construct, the inclusion of a Paragraph IV certification in an ANDA constitutes an "artificial" statutory act of infringement under 35 U.S.C. § 271(e)(2), and thus entitles the patent holder to file an infringement action in federal court. This system allows for adjudication of questions of patent validity and infringement despite the absence of any actual FDA-approved and marketed generic drug product.⁵

In this case, Ranbaxy submitted an ANDA for a generic drug containing "micronized" fenofibrate, which is also an active ingredient in Antara. Because Antara is a drug claimed in a

³ Under Hatch-Waxman, most patentees and NDA holders must list the patents that are related to their approved drugs in the FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations" publication, also known as the "Orange Book." *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1344 (Fed. Cir. 2004) (*citing* 21 U.S.C. § 355(b)(1)).

Reciprocally, a generic drug company has an obligation to consult the Orange Book before filing an ANDA, and to certify either that: (1) no patent information is listed in the Orange Book for their proposed generic drug; (2) the listed patents have expired; (3) the listed patents will expire before the generic company markets its product; or (4) the listed patents are invalid or will not be infringed by the generic drug (a "Paragraph IV certification"). *Id.* (*citing* 21 U.S.C. § 355(j)(2)(A)(I)-(IV)).

⁴ See *Abbott Labs., Inc. v. Apotex, Inc.*, 725 F. Supp. 2d 724, 726-727 (N.D. Ill. 2010) (*citing* 21 U.S.C.S. §§ 355(j)(2)(B) and 355(j)(2)(B)(iv)(II)).

⁵ Artificial infringement should not be confused with a final adjudication of infringement. The concept of artificial infringement was created in this context to enable the federal courts to consider an infringement claim before a generic ANDA product has actually gone to market without running afoul of the Constitution's "case or controversy" requirement. *Glaxo*, 376 F.3d at 1351; *Eli Lilly & Co. v. Medtronic*, 496 U.S. 661, 678 (1990) (noting that § 271(e)(2) creates a "highly artificial" species of infringement, and that its purpose "is to enable the judicial adjudication upon which the ANDA and paper NDA schemes depend").

patent – namely, the ‘574 Patent – Ranbaxy included a Paragraph IV certification in its ANDA, and sent a Paragraph IV letter to Lupin Atlantis. This letter explains why, in Ranbaxy’s view, its ANDA product does not infringe upon the ‘574 Patent. Under § 271(e)(2), Ranbaxy’s inclusion of the Paragraph IV certification in its ANDA created an artificial act of infringement, entitling Lupin Atlantis to file the instant lawsuit.

Ranbaxy moves to dismiss Lupin Atlantis’s infringement claim on the ground that Ranbaxy’s ANDA is clear on its face (and will control any generic product that Ranbaxy will ultimately produce), and the product that is described therein cannot be interpreted as infringing upon the ‘547 Patent. In essence, Ranbaxy asks the Court to compare Ranbaxy’s ANDA to the ‘574 Patent, and to hold that Lupin Atlantis’s Complaint fails to state a claim upon which relief can be granted because – for the reasons identified in Ranbaxy’s Paragraph IV certification – the generic drug described in the ANDA simply would and could not infringe.

As one might well expect, Lupin Atlantis counters that it would be precipitous for the Court to dismiss the infringement claim, given that (1) Lupin Atlantis did not have access to or rely upon Ranbaxy’s ANDA in drafting its Complaint; (2) the ANDA, including the Paragraph IV certification, was drafted by Ranbaxy, and therefore cannot be taken for its truth as sufficient evidence of non-infringement; and (3) determining whether there is actual infringement requires that the Court consider information that is not yet available and indeed could not be considered at this stage in the litigation.

LEGAL STANDARDS

A motion to dismiss pursuant to FED. R. Civ. P. 12(b)(6) tests the legal sufficiency of a

complaint. *Conley v. Gibson*, 355 U.S. 41, 45-46 (1957). While Rule 8 of the Federal Rules of Civil Procedure requires only “a short and plain statement of the claim showing that the pleader is entitled to relief,” FED. R. CIV. P. 8(a)(2), in order to “give the defendant fair notice of what the ... claim is and the grounds upon which it rests,” *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (quoting *Conley*, 355 U.S. at 47), the plaintiff must provide “more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.” *Id.* (citations omitted). Specifically, “[f]actual allegations must be enough to raise a right to relief above the speculative level” *Id.* at 1965 (citations omitted). To survive a motion to dismiss, a civil complaint must allege “factual content [that] allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1950-51 (2009) (confirming that *Twombly* applies to all civil cases).

To be sure, however, a complaint need not be “a model of the careful drafter’s art,” nor must it “pin plaintiffs’ claim for relief to a precise legal theory,” as long as it features “a plausible ‘short and plain’ statement of the plaintiff’s claim.” *Skinner v. Switzer*, 179 L. Ed. 2d 233, 242 (2011); *see also Matrixx Initiatives, Inc. v. Siracusano*, 179 L. Ed. 2d 398, 414 at n. 12 (2011) (emphasizing that in order “to survive a motion to dismiss, respondents need only allege ‘enough facts to state a claim to relief that is plausible on its face’”) (quoting *Twombly*, 550 U.S. at 570)).

DISCUSSION

In *Phonometrics, Inc. v. Hospitality Franchise Sys.*, 203 F.3d 790 (Fed. Cir. 2000), the Court of Appeals for the Federal Circuit provided a straightforward five-part test for considering motions to dismiss infringement cases. That Court held that a complaint alleging infringement

should generally survive a motion to dismiss so long as it: (1) alleges ownership of the asserted patent; (2) names each defendant; (3) cites a patent that is allegedly infringed; (4) describes the means by which defendants allegedly infringe the asserted patent; and (5) points to the specific sections of the patent laws that are involved. *Id.* at 794. Lupin Atlantis's Complaint meets each of these simple requirements.⁶

Moreover, it could be argued that the Court should not even consider the contents of Ranbaxy's ANDA at this stage, given that Lupin Atlantis did not explicitly rely on the ANDA in drafting its Complaint.⁷ Even if the Court does consider Ranbaxy's ANDA, it cannot do so for

⁶ The *Phonometrics* test has been applied by other district courts in this Circuit. See, e.g., *Schreiber v. Eli Lilly & Co.*, 2006 U.S. Dist. LEXIS 13477 (E.D.Pa. 2006) (denying motion to dismiss where plaintiffs' complaint satisfied the five-part test); *CIMA Labs v. Actavis Group*, 2007 U.S. Dist. LEXIS 41516 (D.N.J. 2007) (denying a similar motion to dismiss on the ground that plaintiff had clearly pled that it was licensed to bring the action, and that defendant had filed an ANDA with a Paragraph IV certification).

Ranbaxy argues that each of these cases was decided before the Supreme Court issued its opinions in *Twombly* and *Iqbal*, which, according to Ranbaxy, should invalidate the five-part *Phonometrics* test. As Lupin Atlantis observes, however, the Court of Appeals for the Federal Circuit has continued to apply its five-part *Phonometrics* test in the wake of *Twombly*. See *McZeal v. Sprint Nextel Corp.*, 501 F.3d 1354, 1357 (Fed. Cir. 2007). District courts have also continued to cite *Phonometrics* in ruling on motions to dismiss infringement actions. See, e.g., *Vellata LLC v. Best Buy*, 2011 U.S. Dist. LEXIS 3248 at *10-11 (C.D. Cal. January 7, 2011) (denying motion to dismiss because plaintiff's complaint met the requirements of *Phonometrics*, and "nothing more is required"); *Apple, Inc. v. Eforcity Corp.*, 2011 U.S. Dist. LEXIS 39644 at *6 (N.D. Cal. April 5, 2011) (denying motion to dismiss where the complaint satisfied the five basic *Phonometrics* requirements).

⁷ In *CIMA Labs*, 2007 U.S. Dist. LEXIS 41516 at *12, the court observed that because the plaintiffs' references to the defendant's ANDA were merely to the fact of its filing and to summarize its general contents (as gleaned from defendant's Paragraph IV notice letter), the plaintiffs did not "explicitly rely" on the ANDA, and the ANDA should not be considered in ruling on a motion to dismiss. *Id.* (quoting *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997)).

Here, Lupin Atlantis claims that it had no access to Ranbaxy's ANDA prior to filing its Complaint. The parties dispute whether Ranbaxy's offer to provide Lupin Atlantis with limited access was reasonable, a question not relevant to the resolution of this Motion.

the truth of its contents.⁸ (The Court cannot hold, in other words, that Lupin Atlantis has failed to state a claim because Ranbaxy's Paragraph IV certification establishes, as a factual matter, that Ranbaxy's proposed generic product will not infringe upon the '574 Patent.) This conclusion is underscored by the fact that Ranbaxy actually drafted the ANDA itself – and no judicial cynicism is required to consider that Ranbaxy may have done so with the specific intention of avoiding or forestalling any infringement action.

Finally, an infringement adjudication cannot be completed merely by reviewing the ANDA, and without taking into account any other evidence – including, most notably, expert testimony. The risk of doing so can be seen in, for example, *Astra Aktiebolag, et al. v. Andrx Pharm., Inc., et al.*, 222 F. Supp.2d 423 (S.D.N.Y. 2002). There, the court found that although the defendant had asserted, as the basis of its non-infringement defense, that its ANDA described a product that would lack the distinctive “inert subcoating” that was an essential element of a drug covered by several of the plaintiff’s patents, the full record ultimately indicated that when the defendant’s generic drug was manufactured, it did, in fact, contain such a subcoating. Had the court disposed of the case at the motion to dismiss stage, on the basis of the defendant’s ANDA alone, obviously it would not have heard or considered expert testimony relating to the

⁸ Our Court of Appeals has regularly held that a district court, in ruling on a motion to dismiss under to Rule 12(b)(6), can only consider materials outside the pleadings to establish the truth of their existence, not the truth of their contents. *See, e.g., Lum v. Bank of America*, 361 F.3d 217, 222 n. 3 (3d Cir. 2004) (courts should not consider deposition testimony for its truth at the motion to dismiss stage); *Oran v. Stafford*, 226 F.3d 275, 289 (3d Cir. 2000) (courts may take judicial notice of SEC filings only to determine what those documents stated, not for their truth); *Southern Cross Overseas Agencies v. Wah Kwong Shipping Group, Ltd.*, 181 F.3d 410, 427 n.7 (3d Cir. 1999) (drawing a distinction between taking judicial notice of the *existence* of prior proceedings versus taking judicial notice of the truth of facts averred in prior proceedings).

question of infringement in fact, and would have reached an improvident result.⁹

CONCLUSION

Lupin Atlantis has met the pleading requirements for a patent infringement action. The text of Ranbaxy's ANDA, read in conjunction with the '574 Patent, cannot provide the only basis for the early dismissal of Lupin Atlantis's claim. Ranbaxy's Motion to Dismiss will be denied.

An Order to this effect follows.

BY THE COURT:



GENE E.K. PRATTER
UNITED STATES DISTRICT JUDGE

⁹ Although the Court certainly has no reason to suspect bad faith on the part of Ranbaxy, it is not unknown for a generic manufacturer to file a Paragraph IV certification that is scientifically flawed or otherwise baseless. *See, e.g., Takeda Chem. Indus. v. Mylan Labs.*, 549 F.3d 1381 (Fed. Cir. 2008) (affirming district court's decision to award fees and expenses to the defendant, based partly on bad faith in drafting Paragraph IV certifications).

Ranbaxy cites *Bayer AG v. Elan Pharm. Res. Corp.*, 212 F.3d 1241 (Fed. Cir. 2000), for the proposition that a defendant's ANDA may control the question of infringement, but its reliance on that case is mistaken. *Bayer* was decided in the summary judgment context, after a district court had already considered evidence outside of the ANDA, and did not address whether a district court can dismiss a complaint based upon its own interpretation of the ANDA and a contested patent. In fact, Ranbaxy has identified no cases that support this theory.